SECTION 6

- VACCINE DELIVERY -

The Vaccine Delivery Section describes the system that will be used to order, store, distribute, track and administer influenza vaccine during a pandemic. In the event of a pandemic, influenza vaccine in Massachusetts will be distributed using the established vaccine distribution system, with contingency plans for storage, transport and security for vaccines. Vaccine will be administered at the local level to priority groups determined by the Commissioner of Public Health. Local communities/local coalitions have the responsibility to plan and implement Emergency Dispensing Sites (EDS) for administration of influenza vaccine to priority groups in their jurisdictions.

The amount of vaccine that will have to be managed (ordered, stored, distributed and accounted for) by the Massachusetts Department of Public Health (MDPH) Vaccine Unit will be affected by the manufacturers' ability to produce and distribute vaccine.

Assumptions

This Vaccine Delivery Plan is based on the following assumptions:

- There will be a minimum of 4 – 6 months between a novel virus alert and the availability of vaccine. When vaccine does become available, it will be distributed in multiple shipments, over time, as it is manufactured. Vaccine shortages are likely to exist, especially early during a pandemic.
- Based on information that we have received from CDC, Massachusetts can expect 45,000 – 460,000 doses/month for 1- 2 years. The number of doses available each month will depend on the potency of the vaccine and the vaccine manufacturing capacity at the time.
- Administration of two doses, 30 days apart, will likely be necessary in some or all target groups for optimal immunologic response.
- All publicly purchased influenza vaccine, whether purchased with federal or state funds, will be distributed through MDPH. It is likely that the first doses of influenza vaccine available in a pandemic will be publicly purchased.
- All influenza vaccine, whether publicly or privately purchased, will be administered by providers, according to the priorities set by the Commissioner of Public Health, pursuant to MGL Chapter 111, Section 5A.
- Medicare and Medicaid will be billed for reimbursement for state-purchased and privately purchased vaccine, where applicable.
- The target population for influenza vaccine will initially be prioritized and eventually expanded to the entire population, as vaccine becomes available.
- The priority groups for vaccine will be based on the priority groups recommended of the U.S. Department of Health and Human Services (DHHS). This list may change on short notice depending upon the epidemiologic and clinical features of the pandemic disease.
- In addition to distributing vaccine, MDPH and local health departments/local coalitions will have plans in place to administer vaccine to residents based on the established Priority Groups.
- Administration of vaccine to priority groups and the general public will occur at the local level; the responsibility of the MDPH Vaccine Unit is to ensure the efficient distribution of viable vaccine to 160 local vaccine distributors, as described below.
- Influenza vaccine will be distributed in 10-dose vials.

- Because there is likely to be a moderate to severe shortage of vaccine, at least in the early phases of the epidemic, security for the vaccine must be addressed.
- A system for monitoring vaccine coverage will have to be developed.
- The current Vaccine Adverse Event Reporting System (VAERS) system will be used to monitor vaccine safety.
- While distribution of all other vaccines will be maintained during the pandemic, inventories of non-influenza vaccine will be reduced at the regional and local distributor sites.
- Public education will be an important part of the immunization campaign.

INTERPANDEMIC PERIOD

1. Increase Influenza Vaccination Coverage

MDPH will continue to work with the Massachusetts Quality Improvement Organization (MassPRO), the Massachusetts Medical Society, the Massachusetts Association of Health Plans, the Massachusetts Hospital Association and other members of the Massachusetts Adult Immunization Coalition to increase influenza vaccination rates in Massachusetts as follows to reduce the annual toll from influenza, enhance the existing vaccine delivery infrastructure and facilitate access to high-risk populations when the pandemic occurs:

a. 90% of non-institutionalized adults 50 years of age an older and 60% of high-risk adults 18-49 years of age will receive an annual influenza vaccination, as measured by the BRFSS.

b. 90% of institutionalized chronically ill and elderly adults will receive an annual influenza vaccination, as measured by the annual Massachusetts Executive Office of Elder Affairs.

2. Increase Pneumococcal Vaccination Coverage

MDPH will continue to work with MassPRO, the Massachusetts Medical Society, the Massachusetts Association of Health Plans, the Massachusetts Hospital Association and other members of the Massachusetts Adult Immunization Coalition to increase pneumococcal vaccination rates in Massachusetts as follows to reduce the incidence and severity of secondary bacterial infections now and during the next pandemic:

a. 90% of non-institutionalized adults 65 years of age an older and 60% of high-risk adults 18-64 years of age will receive a pneumococcal vaccination, as measured by the BRFSS.

b. 90% of institutionalized chronically ill and elderly adults will receive a pneumococcal vaccination, as measured by the annual Massachusetts Executive Office of Elder Affairs.

3. Priority Groups for Vaccination during the Pandemic

Pursuant to MGL Chapter 111, Section 5A, the commissioner of public health can issue rules and priorities for the distribution and use of vaccine in the Commonwealth. Vaccine will be prioritized based on national recommendations and refined to meet the specific needs of Massachusetts. The following prioritized groups are based on recommendations by the U.S. Department of Health and Human Services (DHHS) and will be reexamined at the time of a pandemic alert when epidemiologic data about the pandemic virus are available. It is likely that subprioritization will be necessary and will be the responsibility of local communities. The groups eligible for vaccine will expand over time as more vaccine becomes available.

a. Vaccine Priority Group Recommendations (US DHHS 2005)

The estimated number for each group is based on Massachusetts's proportion of the U.S. population (2.2%) and applied to the U.S. estimates for each group (rounded to the nearest thousand).

Tier	Subtier	Population (est. # in Massachusetts)	Rationale
1	A	• Vaccine and antiviral manufacturers and others essential to manufacturing and critical support (?) • Medical workers and public health workers who are involved in direct patient contact, other support services essential for direct patient care, and vaccinators (176,000 – 198,000)	• Need to assure maximum production of vaccine and antiviral drugs • Healthcare workers are required for quality medical care (studies show outcome is associated with staff-to-patient ratios). There is little surge capacity among healthcare sector personnel to meet increased demand
	B	• Persons ≥ 65 years with 1 or more influenza high-risk conditions, not including essential hypertension (400,000) • Persons 6 months to 64 years with 2 or more influenza high-risk conditions, not including essential hypertension by vaccination (152,000) • Persons 6 months or older with history of hospitalization for pneumonia or influenza or other influenza high-risk condition in the past year (16,000)	• These groups are at high risk of hospitalization and death. Excludes elderly in nursing homes and those who are immunocompromised and would not likely be protected.
	C	• Pregnant women (66,000) • Household contacts of severely immunocompromised persons who would not be vaccinated due to likely poor response to vaccine (43,000 with transplants, AIDS, and incident cancer x 1.4 household contacts per person = 60,000) • Household contacts of children < 6 month olds (110,000)	• In past pandemics and for annual influenza, pregnant women have been at high risk; vaccination will also protect the infant who cannot receive vaccine. • Vaccination of household contacts of immunocompromised and young infants will decrease risk of exposure and infection among those who cannot be directly protected by vaccination
	D	• Public health emergency response workers critical to pandemic response (assumed one-third of estimated public health workforce = 3,000) • Key government leaders (?)	• Critical to implement pandemic response such as providing vaccinations and managing/monitoring response activities • Preserving decision-making capacity also critical for managing and implementing a response
2	A	• Healthy 65 years and older (390,000) • 6 months to 64 years with 1 high-risk condition (788,000) • 6-23 months old, healthy (123,000)	• Groups that are also at increased risk but not as high risk as population in Tier 1B

	B	• Other public health emergency responders (7,000 = remaining two-thirds of public health work force) • Public safety workers including police, fire, 911 dispatchers, and correctional facility staff (66,000) • Utility workers essential for maintenance of power, water, and sewage system functioning (8,000) • Transportation workers transporting fuel, water, food, and medical supplies as well as public ground public transportation (84,000) • Telecommunications/IT for essential network operations and maintenance (24,000)	• Includes critical infrastructure groups that have impact on maintaining health (e.g., public safety or transportation of medical supplies and food); implementing a pandemic response; and on maintaining societal functions
3		• Other key government health decision-makers (estimated number not yet determined) • Funeral directors/embalmers (1,400)	• Other important societal groups for a pandemic response but of lower priority
4		• Healthy persons 2-64 years not included in above categories (3.95 million)	• All persons not included in other groups based on objective to vaccinate all those who want protection

b. Definitions and rationales for priority groups

i. Healthcare workers and essential healthcare support staff

Definition

Healthcare workers (HCW) with direct patient contact (including acute-care hospitals, nursing homes, skilled nursing facilities, urgent care centers, physician's offices, clinics, home care, blood collection centers, and Emergency Medical Services (EMS) and a proportion of persons working in essential healthcare support services needed to maintain healthcare services (e.g. dietary, housekeeping, admissions, blood collection center staff, etc.). Also included are healthcare workers in public health with direct patient contact, including those who may administer vaccine or distribute influenza antiviral medications, and essential public health support staff for these workers (e.g. vaccine distribution staff, clinic support staff and volunteers).

Rationale

The pandemic is expected to have substantial impact on the healthcare system with large increases in demand for healthcare services placed on top of existing demand. HCW will be treating influenza-infected patients and will be at risk of repeated exposures. Further, surge capacity in this sector is low. To encourage continued work in a high-exposure setting and to help lessen the risk of healthcare workers transmitting influenza to other patients and HCW family members, this group was highly prioritized. In addition, increases in bed/nurse ratios have been associated with increases in overall patient mortality. Thus, substantial absenteeism may affect overall patient care and outcomes.

ii. Groups at high risk of influenza complications

Definition

Persons 2-64 years with a medical condition for which influenza vaccine is recommended and all persons 6-23 months and 65 years and older. Excludes nursing home residents and severely immunocompromised persons who would not be expected to respond well to vaccination.

Rationale

These groups were prioritized based on their risk of influenza-related hospitalization and death and also their likelihood of vaccine response. Information from prior pandemics was used whenever possible, but information from interpandemic years was also considered. Nursing home residents and severely immunocompromised persons would be prioritized for antiviral treatment and/or prophylaxis and vaccination of healthcare workers and household contacts who are most likely to transmit influenza to these high risk groups.

iii. Critical infrastructure

Definitions and rationale

Those critical infrastructure sectors that fulfill one or more of the following criteria: have increased demand placed on them during a pandemic, directly support reduction in deaths and hospitalization; function is critical to support the healthcare sector and other emergency services, and/or supply basic necessities and services critical to support of life and healthcare or emergency services. Groups included in critical infrastructure are needed to respond to a pandemic and to minimize morbidity and mortality, and include the following sectors:

- Persons directly involved with influenza vaccine and antiviral medication manufacturing and distribution and essential support services and suppliers (e.g., growers of pathogen-free eggs for growth of vaccine virus) production activities
- Key government leaders and health decision-makers who will be needed to quickly move policy forward on pandemic prevention and control efforts
- Public safety workers (firefighters, police, and correctional facility staff, including dispatchers) are critical to maintaining social functioning and order and will contribute to a pandemic response, for example by ensuring order at vaccination clinics and responding to medical emergencies
- Utility service workers (water, power, and sewage management) are prioritized as the services they provide are also essential to the healthcare system as well as to preventing additional illnesses from lack of these services unrelated to a pandemic.
- Transportation workers who maintain critical supplies of food, water, fuel, and medical equipment and who provide public transportation, which is essential for provision of medical care and transportation of healthcare workers to work and transportation of ill persons for care
- Telecommunication and information technology services critical for maintenance and repairs of these systems are also essential as these systems are now critical for accessing and delivering medical care and in support of all other critical infrastructure
- Mortuary services will be substantially impacted due to the increased numbers of deaths from a pandemic and the fact that impact will be high in the elderly, a growing segment of the population

iv. Public health emergency response workers

Definition

This group includes persons who do not have direct patient care duties, but who are essential for surveillance for influenza, assessment of the pandemic impact, allocation of public health resources for the pandemic response, development and implementation of public health policy as part of the response, and development of guidance as the pandemic progresses.

Rationale

Persons in this sector have been critical for past influenza vaccine pandemics and influenza vaccine shortages and little surge capacity may be available during a public health emergency such as a pandemic.

v. Persons in skilled nursing facilities

Definition

Patients residing in skilled nursing facilities. Not included in this group are persons in other residential settings (e.g., assisted living) who are more likely to be mobile, in a setting that is less closed, and have decentralized healthcare.

Rationale

This group was not prioritized for vaccine because of the medical literature finding poor response to vaccination and occurrence of outbreaks even in the setting of high vaccination rates. Other studies have suggested that vaccination of healthcare workers may be a more effective strategy to prevent influenza in this group. Further, surveillance for influenza can be conducted in this group and antiviral medications used widely for prophylaxis and treatment. Ill visitors and staff should also be restricted from visiting nursing home facilities during outbreaks of pandemic influenza. This strategy for pandemic influenza vaccine differs from the interpandemic vaccination strategy of aggressively vaccinating nursing home residents. The rationale considers several factors: 1) these populations are less likely to benefit from vaccine than other groups who are also at high risk; 2) other prevention strategies feasible for this group are not possible among other high-risk groups; 3) the overall morbidity and mortality from pandemic is likely to severely impact other groups of persons who would be expected to have a better response to the vaccine; and 4) a more severe shortage of vaccine is anticipated.

vi. Severely immunocompromised persons

Definition

Persons who are undergoing or who have recently undergone bone marrow transplantation and others with severe immunodeficiency (e.g., AIDS patients with CD4 counts <50, children with severe combined immunodeficiency (SCID) syndrome, recent bone marrow transplant patients). The numbers of persons in these categories is likely much smaller than the anticipated number assumed in tiering above, but sources for more specific estimates have not been identified.

Rationale

These groups have a lower likelihood of responding to influenza vaccination. Thus, strategies to prevent severe influenza illness in this group should include vaccination of healthcare workers and household contacts of severely immunocompromised persons and use of antiviral medications. Consideration should be given to prophylaxis of severely immunocompromised persons with influenza antivirals and early antiviral treatment should they become infected.

vii. Children <6 months of age

Rationale

Influenza vaccine is poorly immunogenic in children <6 months and the vaccine is currently not recommended for this group. In addition, influenza antiviral medications are not FDA-approved for use in children <1 year old. Thus, vaccination of household contacts and out-of-home caregivers of children <6 months is recommended to protect this high-risk group.

Note: Education Regarding the Priority Groups List for Receipt of Vaccine

Special attention must be paid to educating the general public about the Priority Groups List for receipt of vaccine, including the rationale for the list, the process by which the decisions were made, and what other control measures people can take until influenza vaccine is available for everyone. Please see Section 8: Communications for specific information regarding the plan to educate the general public about the priority groups.

c. Plan to Provide Influenza Vaccine to Priority Groups Given Moderate to Severe Vaccine Shortages

At least initially, all influenza vaccine will come through MDPH and will be distributed through the existing state vaccine distribution system. All public and private employers of essential personnel (health care workers, public health and public safety workers, and utility, transportation and telecommunications/IT workers) are responsible for developing continuity of operations plan and prioritizing their personnel for vaccination.

Tier 1A. Healthcare workers and essential healthcare support staff

In both moderate and severe vaccine shortages, hospitals are responsible for developing workforce protections plans to administer vaccine to their employees, and to monitor and document the vaccination status of those employees. In order to respond effectively to the changing availability of vaccine, hospital workforce protection plans should include a tiered plan for prioritizing employees for vaccination, based on the amount of contact with patients and the type of patients they care for. Hospitals will pick up vaccine from their local vaccine distributor, which, in most cases, is the local health department. MDPH will work with hospitals and the Massachusetts Hospital Association to determine the feasibility of hospitals administering vaccine to the families of employees as part of their workforce protection plan. The alternative would be for hospitals to coordinate vaccination of employee families with the local health department.

Smaller health care institutions and agencies (long-term care facilities, provider offices, clinics, community health centers, home health agencies, etc.) should coordinate plans to vaccinate their employees with their local health departments (LHD). This may include receiving the vaccine from the LHD, with the institution/agency being responsible for vaccinating it's personnel.

Tiers 1B. and 1C. Persons at Highest Risk and Their Contacts

Persons at highest risk for complication and their contacts will be vaccinated in public clinics and by their providers. Hospitals are responsible for vaccination of hospitalized patients.

Tier 1D. Public Health Emergency Response Workers and Key Government Leaders

Local health departments will be responsible for vaccinating municipal public health workers and government leaders. MDPH will be responsible for vaccinating state public health workers and state government leaders.

Tier 2A. Other High Risk Persons

Persons at risk for complications from influenza will be vaccinated in public clinics and by their providers. Hospitals are responsible for vaccinating hospitalized patients.

Tier 2B. Essential Personnel

- Public Health Workers - Local health departments will be responsible for vaccinating municipal public health workers and government leaders. MDPH will be responsible for vaccinating state public health workers and government leaders.
- Public Safety Workers (police, fire, correction facility personnel, etc.) - Local health departments will be responsible for vaccinating municipal public safety workers. State agencies will be responsible for vaccinating their employees (by their own occupational health staff, or through arrangements with the local health departments, or with visiting nurse associations (VNAs) or private health services agencies).
- Utility, transportation and telecommunication/IT workers – Companies will be responsible for arranging for vaccination of their employees (by their own occupational health staff, or through arrangements with the local health departments, or with visiting nurse associations (VNAs) or private health services agencies).

Tier 3. Funeral Directors/Embalmers

Funeral directors and embalmers should make arrangements to be vaccinated by their local health department. MDPH will be responsible for vaccinating staff of the State Medical Examiners Office.

Tier 4. Healthy People 2 – 64 years of age Not Included in the Above Categories

The general public will be vaccinated in public clinics or by their providers. Local communities or regional coalitions are responsible for planning and implementing Emergency Dispensing Sites to administer vaccine to the general public when sufficient vaccine is available. Private providers may also receive vaccine to vaccinate their patients who fall into this category.

4. Emergency Dispensing Sites (EDS)

All communities are required to have plans in place to implement emergency dispensing sites for residents in their community. An appendix, *Emergency Dispensing Site Management and Operations,* to the *Template for Local Infectious Disease Emergency Planning and Response* (**www.mass.gov/dph/topics/bioterrorism/idep.doc**) provides guidance to local communities on planning and implementing emergency dispensing sites. MDPH provides technical assistance to local communities on using the guidance to develop their plans.

While MDPH will provide vaccine, it is unclear who is responsible for all other clinic supplies, including syringes. It is unlikely that the SNS will provide clinic supplies. It must be determined who is responsible for syringes, sharps containers and other supplies necessary for running vaccination clinics.

A. Volunteers

Local EDS plans include a list of health care workers and institutions, and non-medical volunteers, who will staff their EDS, as well as a call-down system for their volunteers. Local EDS plans include workforce protection plans for vaccination of all volunteers and their families.

MDPH has developed templates for emergency public health orders to quickly rescind licensing and credentialing requirements to meet needs for vaccinators and other health care providers.

Depending upon the extent of the event and the need for vaccinators, volunteers will be called up in a tiered manner, first calling upon licensed health care professionals, and then going down the list, as need dictates:

a. Personnel who are currently licensed to administer vaccine and dispense medication:

- Physicians
- Registered nurses
- Nurse practitioners and other advance practice nurses
- Licensed practical nurses
- Physician assistants
- Pharmacists
- Dentists

b. Personnel for whom administering vaccine or dispensing medication would constitute an expanded role:

- Emergency medical technicians and paramedics
- First responders
- Veterinarians

c. Personnel who are not licensed or certified to administer vaccines or dispense medications, but who have received some medical training:

- Retired physicians, nurses, pharmacists, etc, who have let their license expire
- Medical assistants, nursing assistants, pharmacy technicians or medical technicians
- Medical, nursing, dental and pharmacy students

d. Lay personnel who have received no or little medical training, but who are capable of being trained to administer vaccine or dispense medication in an emergency situation, following specific protocols.

B. Training for Volunteers

MDPH has provided all local health departments with the videos: *How to Protect Your Vaccine Supply* and *Immunization Techniques*, as well as presenter's notes and skills checklists for pre-event training of volunteer vaccinators and just-in-time training during an event. The *Emergency Dispensing Site Management and Operations* guidance described above includes job action sheets for all volunteer positions to assist with just-in-time training.

C. Emergency Dispensing Site Locations

The *Emergency Dispensing Site Management and Operations* guidance described above includes criteria for communities to use in identifying sites for their EDS. The Massachusetts SNS coordinator maintains a database of the EDS site locations, contact persons, and anticipated clinic throughput for each EDS in every community.

D. Security

MDPH is responsible for security for the vaccine at the State Lab and the regional offices, and during transport between the two.

2 options for security for vaccine during storage and transport include:

- State police through existing agreements between the State Police and the SNS.
- Contracting with a security firm(s).

Local authorities are responsible for security for vaccine during transport between the regional offices and the local distribution sites, and during vaccine storage and distribution at the local distribution sites, and for safety of the volunteers and vaccinees. Local health departments are encouraged to have memoranda of understanding with their local public safety departments to ensure adequate security for vaccine at the local level.

E. Special Populations

Local EDS plans should include provisions for the vaccination of special populations (e.g., the homebound and homeless, people with disabilities (both physical and cognitive), people who speak limited English or languages other than English, etc.). To assist local health officials in providing for special populations in their emergency preparedness planning efforts, MDPH has developed a *Special Populations Guidance for Local Boards of Health* document (http://www.mass.gov/dph/bioterrorism/advisorygrps/pdfs/spop_guidance_5_05.pdf).

Residential schools: Local plans for vaccination of students and staff at boarding schools, colleges and universities may include providing vaccine to the institution for vaccination of their populations on sites, or arrangements to bring the residents to the EDS.

Correctional facilities: MDPH is currently working with the Department of Corrections to address the issue of delivering and administering vaccine to persons held in correctional facilities. Correctional facilities will pick up their vaccine from their local health departments.

Assisted living facilities: In addition, MDPH is working with the Massachusetts Assisted Living Facilities Association to address the issue of delivering and administering vaccine to assisted living centers.

F. Protocols, Forms and Information Sheets

MDPH is responsible for making all protocols, forms and information sheets used in the EDS available on the MDPH influenza web site (www.mass.gov/dph/flu) and on the Homeland and Health Alert Network (HHAN). Local EDS managers are responsible for downloading and copying the forms for use during the EDS. Local EDS planning committees are encouraged to have arrangements with copy businesses for large-scale copying of written materials. A family-based data collection form has been developed for emergency influenza vaccination clinics and is being piloted during emergency clinic exercises. This form will be used until a clinic data collection form is developed by CDC.

G. Emergency Dispensing Site (EDS) Exercises

Communities are required to exercise their EDS plans. When available, influenza vaccine purchased through the SNS will be provided to local communities to exercise their EDS plans during influenza season. Bioterrorism cooperative agreement funds for local communities are tied to identifying EDS sites and developing and exercising their EDS plan.

5. Vaccine Distribution

The MDPH Vaccine Unit, in consultation with the SNS, is responsible for management of vaccine, including coordination of distribution, during a pandemic.

Vaccine will be distributed to public, and eventually private, providers from a central site at the Massachusetts State Laboratory Institute (SLI) in Jamaica Plain, through a network of five regional offices and over 160 local vaccine distributors (primarily local health departments).

The MDPH Vaccine Unit at the SLI is responsible for ordering, receipt, storage, handling, packing, shipping, and disposal of all publicly-purchased vaccines in Massachusetts. Vaccines are ordered

and stored centrally, and transported by courier to the five regional offices. The 160 local distributors then pick up the vaccines from the regional offices. Health care providers pick up their vaccines from the local distribution sites.

A. Vaccine Ordering

CDC will notify MDPH as to how much vaccine is available for Massachusetts. Once the amount of vaccine available is conveyed, distribution of vaccine will be determined based on the established priority groups.

The Executive Pandemic Planning Committee will determine the proportion of vaccine to be held at the SLI for administration to essential State personnel (based on the Priority Group List), and how much vaccine will be available to the cities and towns. MDPH will then notify each city and town accordingly.

B. Vaccine Storage and Distribution

1. State Laboratory Institute (SLI)

Influenza vaccine is shipped to the SLI in cardboard boxes, 100 10-dose vials to a case. Standard operating procedures are in place to safeguard vaccine during power outages and other emergencies. MDPH will provide staff from other MDPH programs, if necessary, to assist with processing vaccine at the SLI. A detailed description of emergency procedures is included in the MDPH document *Vaccine Storage and Accessibility Guidelines*. The MDPH Vaccine Management Unit is developing a plan to provide cross-training to ensure that coordination of vaccine management will continue even when Vaccine Unit staff not available.

2. Regional Offices

As soon as the influenza vaccine arrives at the SLI, it will be transported by courier, in case quantities from the SLI to the regional offices, which are staffed by MDPH personnel. MDPH will provide staff from other MDPH programs, if necessary, to assist with processing vaccine at the SLI. Regional MDPH staff will notify the 160 local distributors that the vaccine is available. Information, including the Vaccine **Information Statements (VISs) and Vaccine** Usage Forms, which document the age groups of the vaccine recipients, will be distributed along with the vaccine.

3. Local Vaccine Distributors

The 160 local vaccine distributors drive to the regional offices to pick up vaccine for providers in their jurisdiction. Security will be the responsibility of the vaccine distributor. They transport the vaccine in an insulated container with cold packs. Local Health Departments and other vaccine distributors maintain a log of all vaccine received from the regional office, including vaccine type, manufacturer, lot number, expiration date, and the quantity of vaccine received.

C. Transportation of Vaccine between SLI and Regional Offices

Vaccines are currently transported between the SLI and the regional offices by a contracted courier service. The courier transports the vaccine in the passenger compartment of the vehicle. Travel time from the SLI to each office is less than one hour, except for the two-hour trip to the western regional office. Up to 75,000 doses can be transported in the passenger compartment of an automobile at one time. Assuming that 12 million doses of vaccine become available, and that 2.8 million doses for the Metro region will remain at the SLI, a total of 9.2 million doses will need to be transported to the other regional offices. The vaccines will be shipped in the cardboard containers in which they are received from the manufacturer.

The table below shows the number of courier trips necessary to transport vaccine to each of the regions, if the vaccine is transported in automobiles.

Number of Courier Trips Necessary to Transport Vaccine To the Regional Offices[1]

Region	Number of Doses	Number of Trips	Cost per Trip[2]	Total Cost
Northeast	**2,200,000**	**30**	**$ 50**	**$ 1,500**
Southeast	**2,440,000**	**33**	**$ 54**	**$ 1,782**
Central	**1,800,000**	**24**	**$ 68**	**$ 1,632**
West	**1,600,000**	**22**	**$ 134**	**$ 2,948**
Boston	**1,150,000**	**16**	**$ 20**	**$ 320**
TOTAL	9,190,000	125		$ 8,182

[1] Assumes 2 doses of vaccine will be available for everyone.
[2] Based on 2005 costs for courier services.

MEMA could call upon MAESF 1, *Transportation* or the State Police to provide transportation of vaccines to supplement the SLI-contracted courier services, if needed.

Unresolved issues:

- *MDPH should get letters of agreement for extended courier services. MEMA will provide assistance with transportation for vaccines only if MDPH is unable to do so.*

D. Vaccine Storage

Vaccine will not be stored in any one place for any length of time. The regional offices currently process and distribute their share of the 745,000 doses within 1 – 3 days of receipt of the vaccine.

Current storage capacity at the SLI and the regional offices could accommodate 3.6 million doses of vaccine, in addition to the usual amount of vaccine stored on regular basis. This capacity may be extended if we decrease inventories of non-influenza vaccine.

Should additional storage be necessary, a refrigerated tractor-trailer truck will be obtained to store additional vaccine. A refrigerated tractor-trailer (45'x 8'x 8') costs approximately $1,000 per month and can be available within a couple of days. The addition of one refrigerated trailer at the SLI would provide adequate storage capacity for the SLI and Metro regions, as well as for vaccine for the central, southeast and western regions until they have room to receive it. Tewksbury Hospital has sufficient capacity to store all the vaccine that would be needed in the northeast region. The table below shows additional off-site storage that may be available to the regional offices, if necessary.

Current Influenza Vaccine Storage Capacity

Region	Population	Current Capacity[1] Doses	Additional Storage Site(s)	Additional Storage Capacity - Doses

SLI	6,000,000	2,500,000	Refrigerated Trailer	As needed
Metro (includes Boston)	1,975,000 (33%)	150,000	SLI refrigerated trailer	As needed
Northeast	1,100,000 (18%)	200,000	Tewksbury Hospital	1,500,000
Southeast	1,220,000 (20%)	200,000	No additional sites	
Central	900,000 (15%)	200,000	Walk-in refrigerator on site	400,000
West	800,000 (13%)	200,000	UMass – Amherst	200,000
	Total	**3,600,000**		

[1]Capacity beyond maximum usual amount of vaccine stored.

Unresolved issues:

- *Plan for obtaining a refrigerated trailer. MDPH should have a Letter of Agreement for a refrigerated trailer on a 24-hour call basis. Although given current projections of the amount of vaccine we would receive monthly, this will probably not be necessary.*
- *Formal agreement for back-up storage in the central and western regions. Letters of Agreement should be signed and reviewed annually.*
- *Amount of vaccine that will be held back at the SLI for vaccination of essential personnel within state agencies (government, state police, state public health and public hospital personnel, etc.).*

E. Security for Vaccine

Security during vaccine storage, transport and distribution must be established. If MDPH is unable to provide adequate security for stored vaccine at the SLI and regional offices, MEMA has the authority to assign that mission to MAESF – 16.

It is likely that vaccine will be received in multiple shipments over a number of months. Security for vaccine will have to be maintained at the SLI and the regional offices, and during transport between those sites. Central storage of vaccine will remain at the SLI.

In order to dispel rumors and decrease panic, it will be important to ensure that the general public has information about the availability of vaccine, how it will be distributed, how decisions were made regarding priority groups for the vaccine, and other measures that can be undertaken to prevent and control influenza. Please see the Communications Section for a full description of how information will be disseminated during a pandemic.

I. Current Security at the SLI and Regional Offices

Currently, all vaccine storage units at the SLI and the regional offices are locked. The central units at the SLI are monitored 24 hours per day, 7 days per week. Security at the regional offices is as follows:

- Metro region: located at the SLI, which is monitored 24 hours/day, 7 days/week.
- Western region: campus security patrols the grounds at UMass Amherst
- Northeast region: security guards patrol the grounds at Tewksbury Hospital
- Southeast region: security guards patrol the grounds at Taunton State Hospital
- Central Office: there are no alarms or security personnel at the central office in West Boylston

- UMass and Tewksbury Hospital have State Campus Police Departments that would be points of contact for security. State Police would augment their services if needed.

II. Enhanced Security at the SLI and Regional Offices

It is the responsibility of MDPH to review the adequacy of the current security measures at the SLI and regional offices and to have a plan in place to enhance security, if needed. Should MDPH become unable to meet the need for security of vaccine, MDPH may request assistance from MEMA.

MEMA has the authority to assign security to *Massachusetts Emergency Support Function (MAESF) 16: Law Enforcement and Security*, of which the State Police are the primary agency. If necessary, the State Police could provide 24-hour details at the SLI for the duration of the time needed. State Police could also provide 24-hour security for stored vaccine, and during distribution of vaccine, at all of the regional offices since they are on state property.

Unresolved issues:

- *Discussion with the MDPH Regional Office Committee on the adequacy of security, jurisdiction for security (especially at the central and southeast offices), and contingency plans for enhanced security, if needed.*

F. Vaccine Accountability

During a pandemic, it will be important to maintain strict accountability for vaccine. At the regional offices and local distributor sites, a special log for influenza vaccine will be maintained to record the manufacturer (assuming multiple manufacturers), lot number, expiration date and quantity of vaccine received and distributed to each site.

At the provider level, a *Vaccine Administration Record* has been developed and is currently in use for mass immunization clinics. The information recorded on the *Vaccine Administration Record* satisfies the requirements for compliance with federal vaccine administration requirements. In order to account for vaccine used the provider tallies the number of doses administered to each of nine age groups, and records the information on the Influenza *Vaccine Usage Form*. These forms are returned through the regional offices to the Vaccine Unit for data entry. Information on doses administered can be totaled and sorted on a daily basis. These forms are being reviewed by the MDPH Vaccine Unit for appropriateness for use in a pandemic situation.

The *Vaccine Administration Record* and the *Vaccine Usage Form* may have to be modified to include information regarding priority group and/or dose (first or second), in addition to the existing age group.

G. Personnel for Vaccine Management

In order to process the additional doses of vaccine and the accompanying paperwork, staffing of the vaccine unit and the regional offices may have to be supplemented. MDPH will provide staff from other MDPH programs, if necessary, to assist with processing vaccine at the SLI. Written protocols for vaccine distribution will be developed to facilitate new or reassigned staff to assist with vaccine distribution functions. During the 4 – 6 months between the pandemic alert and the availability of vaccine, Division and/or reassigned staff will be given specific assignments related to vaccine management, and will be trained by the Vaccine Unit as to their duties.

Additional staffing at the 160 local distributor sites will be the responsibility of the local authorities.

A contract plan is in place to facilitate the hiring of temporary nursing and administrative support staff to assist with answering a hotline, assisting with vaccine distribution, and administering vaccine to state personnel. Using the contract plan, temporary staff can be brought in within 24 – 48 hours. The need for additional staff will depend upon the amount of vaccine that will available for distribution through the public sector. At a minimum, and with no additional resources, the MIP could manage 700,000 doses a month. MDPH, however, should prepare for the possibility of all vaccine being distributed through the public sector.

The following four scenarios regarding vaccine availability are used to estimate additional staffing needs during a pandemic.

No. of Doses Processed by the MIP Vaccine Unit	No. of Additional FTEs Needed		
	Central Office	Regional Offices	Total
Up to 700,000 doses	0	0	0
1 million doses/month	1	5 (1/region)	6 FTEs for 12 months
2 million doses/month	2	10 (2/region)	12 FTEs for 6 months
3 million doses /month	3	15 (3/region)	18 FTEs for 4 months

It would be difficult for the regional offices to find space for more than one or two additional staff. Should more staff be necessary, MDPH will have to find additional space at the regional offices for vaccine distribution.

Unresolved issues:

- *Discussions will be held with the MDPH Regional Office Committees to explore alternatives for space for additional staff and vaccine distribution activities.*

H. Access to Emergency Funds

Funds may be needed quickly to pay for vaccines and additional personnel, courier services, and/or space for storage and distribution of vaccines on an emergency basis. A system that enables state agencies to procure emergency commodities or services "…whenever the health, welfare or safety of persons…is threatened" is authorized by 801 CMR 21.00. Departments are required to execute a contract with the entity selected to perform the contract. The appropriate version of the Commonwealth Terms and Conditions and a Standard Contract Form should be executed as soon as possible after the need for the emergency commodity or service arises (*The Commonwealth of Massachusetts Procurement Policies and Procedures Handbook)*.

Within the SLI, the SLI Administrative Director has the authority to override the $1,000.00 limit on incidental spending. Following a request by a program within SLI, the Administrative Director will facilitate emergency access to funds for purchase or lease of goods or services.

According to MEMA, two other mechanisms for accessing emergency funds are:

a. At the state level, a Declaration of a Public Health Emergency may be issued. In this case, scripted letters should be available to facilitate a quick turnaround of a budget request by the Commissioner of Public Health.

b. The Governor could issue an Executive Order identifying the need for quick action by all state agencies, including Administration and Finance to release funds necessary to respond to the pandemic.

Medicare Reimbursement

To the extent possible, roster bills will be submitted to Medicare for reimbursement for the cost of administering vaccine to Medicare beneficiaries.

6. System for Monitoring Vaccination Coverage

Until MDPH has a functioning immunization registry, monthly reports of data from the Behavioral Risk Factor Surveillance Survey (BRFSS) will be used to monitor vaccine

coverage, by age. The BRFSS data will be augmented by doses administered data collected by the MDPH Vaccine Unit. When the immunization registry is fully functional, it will be used to monitor vaccine coverage.

7. Legal Authorities to Allow for Implementation of the Plan

A. Declaration of State of Emergency

The statute that authorizes the operations of the Mass. Emergency Management Agency (MEMA) allows the Governor to declare a state of emergency. When this occurs, the Governor may exercise "any and all authority over persons and property, necessary or expedient for meeting said state of emergency." This authority includes but is not limited to "Variance of the terms and conditions of licenses, permits or certificates of registration issued by the commonwealth or any of its agencies or political subdivisions." Chapter 639 of the Acts of 1950, 33 App. § 13-7(o). Like the public health emergency authority discussed below, this authority is broad and would allow for a Governor's order with respect to administration and dispensing of needed medications.

B. Declaration of a Public Health Emergency

Under M.G.L. c. 17, § 2A, if the Governor declares that an emergency exists that is detrimental to the public health, the Commissioner may "take such action and incur such liabilities as he may deem necessary to assure the maintenance of public health and the prevention of disease." This authority is very broad and would allow the Commissioner to issue an order specifying what categories of people could administer or dispense medications to others; what training would be required, etc.

C. Current Authority: Pharmacists

Under current MDPH regulations, registered pharmacists may administer "influenza vaccine and other immunizations designated by the Department," provided that the administration is done pursuant to MDPH guidelines that include training, record keeping, etc. 105 CMR 700.004(B)(6).

D. Immunity from Liability

M.G.L. c. 112, s. 12C states that "no physician or nurse administering immunization or other protective programs under public health programs shall be liable in a civil suit for damages as a result of any act omission on his part in carrying out his duties."

E. Authority to Establish by Written Order, Rules and Priorities for the Distribution and Use of Drugs

M.G.L. c. 111, § 5A provides that when the Commissioner determines that the inoculation of (or administration of a drug to) the general public is necessary and there is a shortage of a needed product, the department may purchase, produce and distribute appropriate products and may establish by written order, rules and priorities for the distribution and use of these products. This authority was used successfully to establish priorities for administration of flu vaccine during the 2004-05 influenza vaccine shortage.

F. Mandatory Vaccination

Before considering mandatory vaccination, other options should be exhausted. MDPH's current regulations governing isolation and quarantine, 105 CMR 300.200, require the exclusion of non-immunized health care workers from their occupations for certain periods of time, depending on the disease (for example, see varicella). For new diseases or ones not currently on the list of those requiring isolation or quarantine, 105 CMR 300.150 allows the Commissioner to "establish isolation and quarantine requirements, on a time-limited basis, of confirmed and suspect cases of diseases or conditions which are newly recognized or recently identified or suspected as a public health concern." This would allow unvaccinated people to be kept apart from patients and employees in health care facilities during a disease outbreak.

Apparently, there is no case law in Massachusetts that addresses the authority of government officials to forcibly vaccinate a person against his or her will. If there were a need to vaccinate health care workers against their will in truly dire circumstances of great public health peril, MDPH could apply for a court order to authorize these vaccinations. However, it is not clear whether a court would order forcible administration of vaccinations.

8. Communications Plan

As in mass immunization with any vaccine, it is predictable that two problems will occur:

a. Any symptom or illness that closely follows immunization will be attributed to the vaccine, and

b. Any febrile respiratory illness following immunization will be viewed as a vaccine failure.

Education of the general public will be an important part of the immunization campaign. *(ED Kilbourne. National Immunization for Pandemic Influenza. Hospital Practice 1976:15-21)*

See Section 6: Communications, of the Massachusetts Influenza Pandemic Plan, for details on communication with the public about the following issues:

- Rationale for priority groups
- Contraindications and possible adverse events from influenza vaccine
- Location of vaccination clinics
- Measures other than vaccine to prevent the spread of influenza

9. Websites

A. MDPH Influenza Web Site

MDPH maintains an influenza web page, with a direct link from the MDPH home page. The Influenza Web Site (www.mass.gov/dph/flu) consists of a home page, and separate pages for Influenza Surveillance, Vaccine Availability, and Information for Consumers, Guidelines and Recommendations for Providers, Pandemic Preparedness and Pneumococcal Disease and Vaccine. This web page has links to the CDC, is continually updated and will be a primary source of information for providers and the public during a pandemic.

B. MassPRO Flu Clinic Web Site

The Massachusetts Quality Improvement Organization maintains an influenza clinic website (http://flu.masspro.org), which lists all public influenza vaccination clinics throughout the state. Users can access clinics in their area by zip code or city/town. During a pandemic, this website can be updated very quickly and will be one source of information on the location and times of community vaccination clinics (local communities are expected to have communications plans as part of their EDS plans to notify the people in their jurisdiction about the times, locations and other information about their public clinics). MassPRO is enhancing the website to allow local communities to update their own information on the website, allowing for more flexibility and timeliness in the posting of information.

10. MDPH Hotline

See the Communications Section of the Plan.

11. Contingency Plan for Investigational New Drug (IND) Provisions

Should an IND vaccine be available during a pandemic, MDPH will follow all protocols for inventory control and record keeping, including signed consent. All protocols, forms and information sheets relating to the IND protocol will be provided to all clinics/providers using the IND vaccine, and will be posted on the MDPH influenza Web Site described above.

12. Mechanism for Tracking Second Doses of Vaccine

When fully functional, the immunization registry will be used to track second doses of vaccine. Until then, vaccination sites will use a paper-based system. A family-based data collection form, which captures need for a second dose, has been developed for emergency influenza vaccination clinics and is being piloted during emergency clinic exercises.

13. Monitoring Adverse Events

The Vaccine Adverse Event Reporting System (VAERS), which is the national vaccine safety surveillance program co-sponsored by FDA and CDC, will be the primary mechanism for monitoring events occurring after vaccination with investigational vaccines (Source: CDC/GSK IND protocol). VAERS forms, VAERS web reporting and information about how to report vaccine adverse events is available at http://vaers.hhs.gov/.

PANDEMIC ALERT

- The Executive Pandemic Planning Committee will review the Massachusetts Pandemic Plan, including the Vaccine Section.
- The MDPH Division of Epidemiology and Immunization, with the State SNS coordinator, will modify the plan as needed to account for updates, if any, on recommended target groups and projected vaccine supply.
- MDPH Center for Emergency Preparedness will notify local communities through the Local Emergency Preparedness Coalitions and via the HAN to review their local pandemic and emergency dispensing site plans.
- MDPH, the SNS and local communities will ensure that human resources and logistics are in place to begin vaccination.

PANDEMIC PERIOD

- MDPH, the SNS and local communities will fully activate the vaccination program as soon as vaccine is available.